

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-x-

ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
COLLEGE OF AMERICAN PATHOLOGISTS;
HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD;
WENDY CHUNG, MD, PhD; HARRY OSTRER, MD;
DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD;
ELLEN MATLOFF, M.S.; ELSA REICH, M.S.;
BREAST CANCER ACTION; BOSTON WOMEN'S
HEALTH BOOK COLLECTIVE; LISBETH CERIANI;
RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE;
VICKY THOMASON; KATHLEEN RAKER,

09 Civ. 4515 (RWS)

ECF Case

Plaintiffs,

v.

DECLARATION OF
BARBARA A. BRENNER

UNITED STATES PATENT AND TRADEMARK
OFFICE; MYRIAD GENETICS; LORRIS BETZ,
ROGER BOYER, JACK BRITTAINE, ARNOLD B.
COMBE, RAYMOND GESTELAND, JAMES U.
JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS,
DAVID W. PERSHING, and MICHAEL K. YOUNG,
in their official capacity as Directors of the University
of Utah Research Foundation,

Defendants.

-x-

1. My name is Barbara A. Brenner. I am Executive Director of Breast Cancer Action ("BCA"). BCA is a Plaintiff in the above-captioned case in its own right and on behalf of its members.

2. Breast Cancer Action is a national not-for-profit organization of approximately 30,000 members. We are dedicated to carrying the voices of people affected by breast cancer in order to inspire and compel the changes necessary to end the breast cancer epidemic. Our

members include breast cancer survivors, family members of people diagnosed with breast cancer, and other people affected by or concerned about breast cancer.

3. BCA advocates for policy changes directed at achieving prevention, finding better treatments, and reducing the incidence of breast cancer, provides information about breast cancer to anyone who needs it via newsletters, web sites, e-mail and a toll-free number, and organizes people to get involved in advocacy to advance its policy goals.

4. This case seeks to invalidate patents that have been granted on the BRCA1 and BRCA2 genes. This goal is central to the mission of BCA. Three of our core principles are: people should be able to participate fully in decisions relating to breast cancer treatment; access to information about breast cancer is vital; and people must have access to quality health care. The patents on the BRCA genes make it impossible to advance these principles. BCA cannot encourage researchers and clinicians to perform BRCA1 and BRCA2 related activities, including genetic testing and research, even when the activities might be aimed at creating new testing methods that Myriad Genetics does not offer or discerning the meaning of uncommon genetic variants. We cannot refer members to or publicize full gene sequencing services at laboratories other than or in addition to Myriad Genetics.

5. The patents limit our work because they are so wide-ranging as to cover the actual BRCA1/2 genetic sequences, mutations, and correlations with cancer, fundamental information that should be shared with all patients, researchers, advocates, and the public. The gene patents have frustrated BCA's advocacy for unfettered research into the causes and treatment of breast cancer. The gene patents also have frustrated BCA's efforts to provide useful information to its members and the public regarding BRCA1/2 genetic testing and information about the significance of BRCA1/2 mutations. For every type of referral we provide, we routinely suggest

more than one place to get help or information. This is important for carrying out BCA's educational mission because it is often valuable for someone affected by breast cancer to obtain a second opinion or access more resources. However, for BRCA full sequencing for patients, we can only make one referral – Myriad Genetics, a company whose practices BCA has often criticized.

6. BCA has had to devote its scarce resources into identifying and addressing the problems that result from the BRCA1/2 gene patents and exclusive genetic testing, including staff time for investigating, writing and publishing articles about these problems and advising women who are facing difficult medical situations because the gene patents prevent alternative testing options or information-sharing. And because the patents extend over the correlation between mutations and hereditary risk of cancer, any publication of that correlation by BCA could be alleged to induce patent infringement, even though one of BCA's main purposes is to educate the public about breast cancer.

7. Many of BCA's members are directly injured by the patents on the BRCA genes. The gene patents create obstacles for patients and their doctors who want information about the BRCA1/2 genes by precluding them from obtaining testing at all or at the laboratory of their choice, from verifying test results at a second lab, or from choosing a laboratory that would share data with researchers. Some of our members have been unable to obtain BRCA genetic testing because of the high cost of the test. Other BCA members face making life-altering decisions without the benefit of a confirmatory test, or have received ambiguous genetic test results that show that they have a genetic variant of uncertain significance. BCA has brought this case on behalf of its members, some of whom are ready, willing, and able to order BRCA1/2 genetic testing and analysis at laboratories other than Myriad Genetics if the patents are invalidated.

Elinor Coleman is one such member. She is a BCA member and breast cancer survivor. In 2004, she was tested through Myriad Genetics and was told she has a variant of uncertain significance. She wants additional analysis of her genes to be performed by a laboratory other than Myriad, and is ready, willing, and able to take action to pursue further testing once the patents are no longer in force.

8. To advance its mission, BCA has long expressed concerns about the BRCA1/2 gene patents and Myriad Genetics' exclusive control over genetic testing. For example, I wrote an article for our February/March 1997 newsletter, raising questions about Myriad's commercial goals in gene patenting and genetic testing and the high price of genetic testing (it cost \$2400 then, and now costs over \$3000). In our May/June 2004 newsletter, we published an article highlighting the differences between testing conducted in the United States and in Europe that have resulted from the more limited enforcement of the patents in Europe. Patents on the BRCA1/2 genes should not determine the availability and quality of genetic testing and the freedom to conduct research.

9. If the patents were invalidated, BCA would immediately use its existing resources to publicize other laboratories for BRCA genetic testing and research opportunities. BCA knows that these alternatives would exist, because it is aware that other plaintiffs in this case, including Dr. Chung and Dr. Ostrer, would engage in new BRCA-related activities if the patents were not a barrier.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and belief.

Executed on August 7, 2009

Barbara A. Brenner
BARBARA A. BRENNER